REMARKS

Claims 1-29 are pending. Claims 22-24 are withdrawn from consideration, and remaining claims 1-21 and 25-29 stand rejected.

Applicant cancels non-elected claims 22-24, as well as claims 10-13, 18-21, and 25-28. Applicant also amends claims 1, 3, 4, 15, and 29. Claim 1 is amended to clarify that the ALA is applied at a lose dose that is effective to kill bacteria without modifying the sebaceous gland. Claim 3 is amended to recite exposing the skin to energy in the range of about 1 to 20 J/cm^2. Support for these amendments can be found throughout the specification, for example, at page 9, line 15 to page 10, line 2. Claim 4 is amended to depend from claim 3, rather than claim 2, and claim 15 is amended to more clearly recite the step of applying ultrasound to drive the ALA into spaces "in the skin." Claim 29 is amended to delete the claimed amount of ALA.

Applicant adds new claim 30, which is generally directed to a method for treating a sebaceous gland disorder in which ALA is applied to the skin at about 0.10 to 1.0 % by weight, and the skin is then exposed to sunlight to activate the ALA. Support for this amendment can be found throughout the specification and in the originally filed claims, for example, in original claims 1 and 29. No new matter is added.

Claims 1-9, 14-17, and 29-30 are now pending. Applicant respectfully requests reconsideration of the present application in view of the amendments set forth above and the remarks below.

Rejection Pursuant to 35 U.S.C. §112

Claims 11 and 13 are rejected pursuant to 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant cancels these claims, thereby obviating the basis for this rejection.

Rejection Pursuant to 35 U.S.C. §102(e)/103(a)

Claims 1-21 and 25-29 are rejected pursuant to 35 U.S.C. §102(e)/103(a) as being anticipated by, or obvious over, U.S. Patent No. 5,955,490 of Kennedy et al. (Kennedy). The Examiner argues that Kennedy discloses a method for treating sebaceous gland disorders substantially as claimed. The Examiner further rejects claims 1-21 and 25-29 as being obvious over WO 95/07077 of Gierskcky in view of Kennedy and U.S. Patent No. 5,713,845 of Tankovich. The Examiner relies on Gierskcky to disclose ALA-PDT therapy as used to treat disorders of internal and external body surfaces, but admits that Gierskcky fails to disclose the treatment of acne using ALA-PDT, as well as some other claimed methods, such as the use of ultrasound to drive the ALA into the spaces in the skin. Thus, the Examiner relies on Kennedy to disclose the use of ALA to treat acne, and Tankovich to disclose a method in which ALA infiltrates into the spaces in the skin, arguing that it would have been obvious to combine these three references to maximize the treatment parameters. Applicants respectfully disagree.

The Present Invention

Applicant has discovered that ALA can be used at very low doses to provide a temporary, but effective acne treatment. The ALA solution can advantageously be sold over-the-counter, and the patient can merely expose themselves to sunlight to activate the ALA. Low-dose treatments offer several advantages over the high-dose methods disclosed by the prior art. In particular, high dose treatments take several hours to maximize accumulation of ALA, requiring long office visits. Light exposure can also be very painful when given at irradiances practical for medical office use, i.e., high enough for treatment exposure less than about 30 minutes. Moreover, multiple treatments can be necessary, requiring several office visits.

Low dose treatments also have a different effect than high dose treatments. In particular, when ALA is applied at low doses, the ALA has an antibiotic effect, wherein any

bacteria present in the skin is killed without affecting the sebaceous gland. Such low dose treatments are thus not effective to treat cancerous tissue, as the tissue will not be destroyed. High dose treatments, on the other hand, have a more permanent effect and can result in the destruction of tissue. High doses of ALA will result in a modification of the sebaceous gland to prevent the accumulation of bacteria therein. Thus, high doses of ALA will not "treat" acne, but rather are used as a cure.

Claims 1-9 and 14-17

Independent claim 1, as amended, recites a method for treating a sebaceous gland disorder that generally includes the steps of topically applying ALA to a section of skin afflicted with a sebaceous gland disorder and exposing the infiltrated section of skin to energy to cause the photosensitizing agent (e.g., the converted ALA) to become photodynamically activated to kill bacteria and thereby treat the sebaceous gland disorder. Claim 1 further requires that the ALA be applied *at a low dose that is effective to kill bacteria without modifying the sebaceous gland.*

Kennedy discloses the use of ALA to detect and/or treat rapidly growing tissue cells and parasites or bacteria. In the Detailed Description of the Invention, Kennedy states that ALA can be topically applied at a dose of between about 2% and 100%. This concentration range, however, is limited for use in treating rapidly growing cells (e.g., cancer) (See col. 9, line 45 to col. 10, line 3). In particular, the ALA is applied to the tissue after the abnormal tissue is removed, and it is used to ***destroy*** any remaining abnormal tissue. While Kennedy is mainly directed toward the treatment of cancer, Kennedy does disclose the use of ALA for treating acne. In particular, Example 8 of Kennedy discloses the use of an ALA solution that is topically applied to the patient's skin at a concentration in the range of about 10% to 20% to evaluate PpIX fluorescence. There is no teaching or suggestion in Kennedy to use a lower dosage of ALA to treat acne, much less to use a dosage that will only kill bacteria without modifying the sebaceous gland. To the contrary, one might expect such a low dosage of ALA to be ineffective. It would also not have been obvious to use a low dosage of ALA since

Kennedy is further limited to treatment in a clinical setting, which necessarily would require a high dose of ALA to provide an effective treatment within the time constraints typically present in office visits. Accordingly, claim 1, as well as claims 2-9 and 14-17 which depend therefrom, distinguish over Kennedy.

Gierskcky likewise discloses a method for treating skin cancer and psoriasis using a high concentration of ALA. In particular, Gierskcky discloses an ALA composition having 10% to 30% ALA that is used to *destroy* tissue. Gierskcky does not teach or suggest using ALA to treat acne, and in fact it would not have been obvious to rely on the teachings of Gierskcky for the treatment of acne according to the method of the present invention since it is undesirable to *destroy* tissue when treating acne. Gierskcky also does not teach or even suggest using lower dosages of ALA, and thus for the same reasons stated above with respect to Kennedy, it would not have been obvious to use such a low dose. Claims 1-9 and 14-17 therefore distinguish over Gierskcky.

Tankovich also fails to teach or suggest a method for treating acne wherein ALA is applied at a low dose that is effective to kill bacteria without modifying the sebaceous gland. To the contrary, Tankovich discloses a topically applied agent that is absorbed by the skin and which *explodes* subdermally upon the application of light thereto. As a result, any tissue in the vicinity of the agent is destroyed. Thus, for the same reasons stated above with respect to Gierskcky, Tankovich cannot be relied on for the treatment of acne since the claimed invention seeks to avoid tissue destruction when treating acne. Accordingly, claims 1-9 and 14-17 distinguish over Tankovich.

Claim 29

Independent claim 29 recites a method for the treatment and prevention of acne in which ALA, combined with a substance which absorbs UV radiation in the UVA or UVB range, is topically applied to the skin and exposed to sunlight in the range of about 1 to about 50 J/cm^2 to cause the ALA to become activated thereby eradicating the bacteria associated with

acne. This advantageously provides sunscreen protection while allowing a patient to treat acne by self-exposure to sunlight. The Applicant of the present invention has discovered that sunlight contains enough irradiance for ALA, thereby eliminating the need for clinical treatments. This treatment method also offers the advantage of being less painful, and it is widely available and much more costly than artificial light sources.

None of the cited references teaches or even suggests using ALA with a UV-absorbing substance, as required by claim 29. Kennedy merely discloses an ALA solution, and does not disclose any UV-absorbing compounds with which the ALA can be combined. While Gierskcky discloses a composition that includes ALA and a chelating agent, Gierskcky does not teach or suggest using any type of sunscreen with ALA. Applicant further notes that it would not have been obvious to modify either Kennedy or Gierskcky to include any type of UV-absorbing substance since neither reference teaches or even suggests using sunlight as the light source to activate the ALA. Moreover, Kennedy or Gierskcky are limited to high dosages that require treatment to take place in a clinical setting.

As previously stated, Tankovich is limited to the topical application of an agent that is effective to *explode* subdermally, upon application of light, to destroy tissue. Tankovich therefore cannot be relied on for the treatment of acne since the claimed invention seeks to avoid tissue destruction. Tankovich further fails to teach or even suggest the use of ALA with any type of sunscreen, and such a composition would not have been obvious to a person having ordinary skill in the art since the use of Tankovich's composition in sunlight would cause serious damage to the patient's skin.

Accordingly, claim 29 therefore distinguishes over the art and represents allowable subject matter.

Claim 30

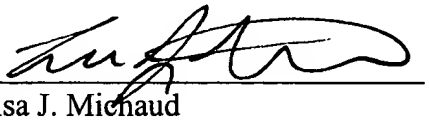
Independent claim 30, which is similar to claim 1, recites a method for treating acne by topically applying ALA at a range of about 0.10 to 1.0% by weight, and exposing the infiltrated section of skin to sunlight to activate the ALA. For the same reasons stated above with respect to claim 1, none of the cited references teaches or even suggests a low-dose method for treating acne. Moreover, for the same reasons set forth with respect to claim 29, none of the references teach or even suggest activating the topically-applied ALA using sunlight.

Conclusion

In view of the amendments and remarks above, Applicant submits that claims 1-9, 14-17, and 29-30 are in condition for allowance. In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with the Examiner is requested. Applicant encourages the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

Respectfully submitted,

Date: August 7, 2003



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